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Attorney for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, NORTHERN DIVISION

RYAN SPENCER an individual; Plaintiff, vs. BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER OY, AND BAYER PHARMA AG Defendants.	**COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL** Case No: 1:15-cv-00063-EJF Magistrate Judge Evelyn J. Furse

COMPLAINT

COMES NOW Plaintiff RYAN SPENCER; an individual, and files this Complaint seeking judgment against Defendants BAYER HEALTHCARE PHARMACEUTICALS INC., BAYER OY, AND BAYER PHARMA AG, (hereinafter collectively "Defendants" or "Bayer") for personal injuries suffered as a proximate result of Plaintiff RYAN SPENCER being prescribed and using the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine system). At all times relevant hereto, Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendants.

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal places of business in states other than the state in which the named Plaintiff resides.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claim occurred, in part, in the Northern District of Utah.

PARTIES

Plaintiff

4. At all relevant times hereto, Plaintiff, RYAN SPENCER, was resident and citizen of Davis County, Utah.

Defendants

5. Defendant Bayer Healthcare Pharmaceuticals Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Defendant Bayer Healthcare Pharmaceuticals Inc. can be served with process through a representative at the SOP Department, Corporation Service Company, Suite 400, 2711 Centerville Road, Wilmington, Delaware 19808.

6. Defendant Bayer Healthcare Pharmaceuticals Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

7. Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals Inc.

8. Defendant Bayer Healthcare Pharmaceuticals Inc. is the holder of the approved New Drug Application (NDA) for contraceptive device Mirena®.

9. Bayer Pharma AG is a corporation and foreign defendant organized and existing in Germany. Bayer Pharma AG designed, developed and researched all Mirena sold by Bayer Healthcare Pharmaceuticals in the United States. From September 1st, 2008 to the present Bayer Pharma AG purchased all Mirena sold in the United States exclusively from Bayer OY and resold the product to Bayer Healthcare Pharmaceuticals.

10. Bayer Pharma AG has agreed to waive formal service of summons on it pursuant to Federal Rule of Civil Procedure 4 and to accept service by registered mail addressed to their representative for service located at:

Bayer Pharma AG
Attn: Eva Gardyan-Eisenlohr
General Counsel
Muellerstrasse 178
13353 Berlin
GERMANY

11. Bayer OY is a corporation and foreign defendant organized and existing in Finland. Prior to September 1st, 2008 Bayer OY sold all Mirena to Bayer Healthcare Pharmaceuticals and its predecessors.

12. Bayer OY has agreed to waive formal service of summons on it pursuant to Federal Rule of Civil Procedure 4 and to accept service by registered mail addressed to their representative for service located at:

Bayer OY
Legal Department
Pansiontie 47/P.O. Box 415
20101 TURKU
FINLAND

13. Bayer is in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the intrauterine contraceptive system, Mirena®.

14. Bayer does business in Utah through the sale of Mirena® and other prescription drugs in the state.

15. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena®.

16. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

17. Mirena® is an intrauterine system that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with asteroid reservoir that releases 20 µg/day of levonorgestrel, a prescription medication used as a contraceptive.

18. The Federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.

19. The system releases levonorgestrel, a synthetic progestrogen, directly into the uterus for birth control. Defendants admit it is not known exactly how Mirena works, but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

20. The Mirena® intrauterine system ("IUS") is designed to be placed within seven (7) days of the first day of menstruation and is approved to remain in the uterus for up to five (5)

years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

21. The package labeling recommends that Mirena® be used in women who have had at least one child.

22. Mirena®'s label does not warn about spontaneous migration of the IUS, but only states that migration may occur if the uterus is perforated during insertion.

23. Mirena®'s label also describes perforation as an "uncommon" event, despite the fact that there are numerous women who have suffered migration and perforation post- insertion, clearly demonstrating this assertion to be false.

24. Defendants have a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

25. In or around December 2009, Bayer was contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private settings by a representative from "Mom Central," a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

26. This Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena®' s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

27. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that

Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

28. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on Mirena®.

29. Finally, Defendants falsely claimed that Mirena required no compliance with a monthly routine.

30. Plaintiff RYAN SPENCER is currently 34 years-old.

31. Plaintiff had the Mirena® product (hereinafter sometimes "PRODUCT") inserted on or about August 23rd, 2012 at Rocky Mountain Women's Health Center in Layton, Utah.

32. After insertion Plaintiff's IUD was confirmed through Plaintiff's self-checking of her strings as well as through an ultrasound at Rocky Mountain Women's Health Center.

33. At some point after the IUD threads were confirmed to be correctly in place, the IUD perforated the Plaintiff's uterus, migrated outside of her uterus and became embedded in her omentum.

34. On May 12th, 2014 Plaintiff presented to Davis Hospital and Medical center with complaint of abdominal pain. Plaintiff underwent an X-Ray of her abdomen confirming that her IUD was no longer located inside her uterus.

35. On May 22nd, 2014 Plaintiff underwent a failed attempt at removing her IUD at Rocky Mountain Womens Health Center.

35. On June 17th, 2014, Plaintiff presented to Davis Hospital and Medical Center in Layton, Utah for her second surgery to remove her misplaced IUD. During this surgery her IUD was located and removed laparoscopically from her omentum.

36. Although Plaintiff followed all instructions accompanying the PRODUCT and used the PRODUCT as directed, after implant of the PRODUCT, Plaintiff suffered serious and

life-threatening side effects and injuries including, but not limited to extreme lower torso pain and related sequelae requiring hospitalization, extensive medical therapy, continuing treatment, physical therapy and medical monitoring. Further personal injuries suffered by Plaintiff include, but are not limited to, pain and suffering, permanent bodily impairment, mental anguish and diminished enjoyment of life.

37. Plaintiff files this lawsuit within two (2) years of first suspecting that the PRODUCT was the cause of appreciable harm sustained by Plaintiff, within two (2) years of first suspecting or having reason to suspect any wrongdoing, and within the applicable limitations period of first discovering their injuries and the wrongful conduct that caused such injuries. Plaintiffs could not by the exercise of reasonable diligence have discovered any wrongdoing, nor could Plaintiff have discovered the causes of her injuries at an earlier time because some injuries occurred without initial perceptible trauma or harm, and when the Plaintiff's injuries were discovered, their causes were not immediately known.

38. Plaintiff did not suspect, nor did she have reason to suspect, that wrongdoing had caused her injuries, nor did Plaintiff have reason to suspect the tortious nature of the conduct causing the injuries, until recently and has filed the herein action well within the applicable statute of limitations period. Plaintiff had no knowledge of the defects in the PRODUCT and the wrongful conduct of Defendants as set forth herein, nor did Plaintiff have access to the information regarding other injuries and complaints in the possession of defendants. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants herein misrepresented and continue to misrepresent to the public, to the medical profession and to the Plaintiff that the PRODUCT is safe and free from serious defects and side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to an earlier discovery of potential causes of action.

FIRST CAUSE OF ACTION:

NEGLIGENCE

39. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

40. Upon information and belief, Defendants failed to use reasonable care in designing Mirena® in that they:

a. failed to properly and thoroughly test Mirena® before releasing the drug to market;

b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Mirena®;

c. failed to conduct sufficient post-market testing and surveillance of Mirena®;

d. designed, manufactured, marketed, advertised, distributed, and sold Mirena® to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Mirena® and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. failed to exercise due care when advertising and promoting Mirena®; and

f. negligently continued to manufacture, market, advertise, and distribute Mirena® after Defendants knew or should have known of its adverse effects.

41. A reasonable manufacturer would or should have known that its risks created by Mirena® are unreasonably greater than that of other contraceptives and that Mirena® has no clinical benefit over such other contraceptives that compensates in whole or part for the increased risk.

42. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SECOND CAUSE OF ACTION:

STRICT LIABILITY

43. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

44. Defendants are manufacturers and/or suppliers of Mirena® and are strictly liable to Plaintiff for manufacturing, designing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, marketing, advertising, distributing, selling and placing Mirena® into the stream of commerce.

45. Mirena®, manufactured and/or supplied by Defendants, was defective in design or formulation in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous. It was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.

46. Mirena® was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

47. Mirena® was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Mirena® created, among other things, a risk of perforation and migration and associated infections or conditions and the Defendants failed to adequately warn of these risks.

48. Mirena® was defective due to inadequate pre-marketing testing.

49. Defendants failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known of the extreme risks associated with Mirena® and continues to promote Mirena® in the absence of those adequate warnings.

50. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

THIRD CAUSE OF ACTION:

BREACH OF IMPLIED WARRANTY

51. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

52. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® as safe for use by the public at large, including Plaintiff, who purchased Mirena®. Defendants knew the use for which their product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

53. Plaintiff reasonably relied on the skill and judgment of the Defendants, and as such their implied warranty, in using Mirena®.

54. Contrary to same, Mirena® was not of merchantable quality or safe or fit for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used.

55. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FOURTH CAUSE OF ACTION:

BREACH OF EXPRESS WARRANTY

56. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

57. The aforementioned designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® were expressly warranted to be safe by Defendants for Plaintiff and members of the public generally. At the time of the making of these express warranties, Defendants had knowledge of the foreseeable purposes for which Mirena® was to be used and Defendants warranted Mirena® to be in all respects safe, effective and proper for such purposes.

58. Mirena® does not conform to these express warranties and representations because Mirena® is not safe or effective and may produce serious side effects.

59. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FIFTH CAUSE OF ACTION:

NEGLIGENT MISREPRESENTATION

60. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

61. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena®, owed a duty to provide accurate and complete information regarding Mirena®.

62. Defendants falsely represented to Plaintiff that Mirena® was a safe and effective contraceptive option. The representations by Defendants were in fact false, as Mirena® is not safe and is dangerous to the health of its users.

63. At the time the aforesaid representations were made, Defendants concealed from Plaintiff and her health care providers, information about the propensity of Mirena® to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of Mirena® despite the lack of information regarding same.

64. These misrepresentations were made by Defendants with the intent to induce Plaintiff to use Mirena®, which caused her injury.

65. At the time of Defendants' misrepresentations and omissions, Plaintiff was ignorant of the falsity of these statements and reasonably believed them to be true.

66. Defendants breached their duties to Plaintiff by providing false, incomplete and/or misleading information regarding their product. Plaintiff reasonably believed Defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Mirena®.

67. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SIXTH CAUSE OF ACTION:

FRAUDULENT MISREPRESENTATION

68. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

69. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® described herein, owed a duty to provide accurate and complete information regarding Mirena®.

70. Defendants fraudulently misrepresented material facts and information regarding Mirena® including, but not limited to, its propensity to cause serious physical harm.

71. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiff was unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

72. Defendants knew this information to be false, incomplete and misleading.

73. Defendants intended to deceive and mislead Plaintiff so that she might rely on these fraudulent misrepresentations.

74. Plaintiff had a right to rely on and did reasonably rely upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

75. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SEVENTH CAUSE OF ACTION:

FRAUD

76. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

77. Defendants had a duty and obligation to disclose to Plaintiff that Mirena® was dangerous and likely to cause serious health consequences to users when used as prescribed.

78. Defendants intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff with the intent to defraud her as herein alleged. Defendants intentionally misrepresented the facts set forth above with the intention that Plaintiff would purchase and use Mirena.

79. Neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

80. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff has proximately sustained damage, as set forth herein.

81. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

REQUEST FOR PUNITIVE DAMAGES

82. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

83. At all times relevant herein, Defendants:

a. knew that Mirena® was dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiff, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiff, her physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of Mirena®; and

d. with full knowledge of the health risks associated with Mirena® and without adequate warnings of the same, manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® for routine use.

84. Defendants, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiff and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiff and the general public.

85. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiff has become liable.

86. As a further direct and proximate result of defects in the PRODUCT and the wrongful conduct, acts, omissions, and fraudulent misrepresentations of Defendants, Plaintiff incurred special damages in the form of, inter alia, the reasonable value of services rendered for medical care for the injuries sustained prior to death.

87. Defendants are liable jointly and/or severally for all general, special and compensatory damages and equitable relief to which Plaintiff is entitled by law. The Plaintiff seeks actual and punitive damages from the Defendants and alleges that conduct of Defendants was committed with knowing, conscious, reckless, deliberate and grossly negligent disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

RELIEF REQUESTED

WHEREFORE Plaintiff prays for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of the Plaintiff, as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount according to proof at the time of trial;

2. Past and future economic and special damages according to proof at trial;

3. Loss of earnings and impaired earning capacity according to proof at trial;

4. Medical expenses, past and future, according to proof at the time of trial;

5. Past and future pain and suffering damages, including mental and emotional stress arising from Plaintiff’s physical injuries, according to proof at the time of trial;

6. Equitable relief as requested and/or as the Court deems just and proper;

7. Declaratory judgment that Defendants are liable to Plaintiff for all future evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendants' wrongdoing;

8. Medical monitoring, whether denominated as damages or in the form of equitable relief according to proof at the time of trial;

9. Punitive or exemplary damages according to proof at the time of trial;

10. Costs of suit incurred herein;

11. Pre-judgment interest as provided by law; and

12. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a jury trial of all issues of fact in this matter.

DATED this 17th day of April, 2015.

EISENBERG GILCHRIST & CUTT

/s/ Christopher P. Higley
Christopher P. Higley

Attorney for Plaintiff

Plaintiff's Address:
2859 W. 2435 S.
Syracuse, UT 84075